

**REMARKS**

The Office Action of January 2, 2004 presents the examination of claims 43, 45, 51, 52 and 63-71. These claims remain pending and are not presently amended.

Information Disclosure Citation

The Examiner has not provided Applicant with an initialed copy of the PTO-1449 form filed with the Information Disclosure Statement filed July 8, 2003. An initialed copy thereof is respectfully requested from the Examiner with the next communication.

Oath alleged defective

The Examiner maintains his position that the Oath or Declaration of the inventors filed in the original application is insufficient because the present application, via preliminary amendment of the parent application 09/371,510 on August 10, 1999, introduced subject matter not attested to as being claimed in the original application.

Applicants similarly maintain their position that they will provide a supplemental Declaration of the inventors as the Examiner has requested at such time as the claims are otherwise considered to be in condition for allowance. Thus, Applicants

request that this issue be held in abeyance until such time as allowability of claimed subject matter is resolved.

Rejection under 35 U.S.C. § 102(e)

The Examiner maintains the rejection of claims 43, 45, 51, 52 and 63-70 and rejects claim 71, under 35 U.S.C. § 102(a) or § 102(e) as anticipated by Johnston et al. '462. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner maintains the instant rejection in view of his position that the present claims are only entitled to a filing date of August 10, 1999. Applicants similarly maintain to the contrary that the present specification, which but for addition of Sequence Listing identifiers is identical to that filed as PCT/SE91/00855 on December 12, 1991, provides adequate written description support and enablement of the invention recited in claims 43, 45, 51, 52 and 63-71.

The test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing. See, *Vas-Cath*, 935 F.2d at 1561 ("Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation").

*Moba B.V. v. Diamond Automation, Inc.*, 66 USPQ2d 1429, 1439 (Fed. Cir. 2003). The assessment is made from the viewpoint of one skilled in the art. *Id.* at 1439.

Applicants submit that one of ordinary skill in the art, reading the present specification, would conclude that the inventors possessed the invention of claims 43, 45, 51, 52 and 63-70 at the time of filing of the PCT/SE91/00855 application. Applicants at this time present evidence, in the form of a Declaration signed by one of the inventors, being an artisan of ordinary skill at the time the invention was made, that one of ordinary skill in the art would indeed conclude that the inventors possessed the invention of claims 43, 45, 51, 52 and 63-70 at the time of filing of the PCT/SE91/00855 application. Accordingly, the present application should be accorded the effective filing date of December 12, 1991 and the Johnston '462 patent is not effective as prior art against the instant claims. Accordingly, the rejection of claims 43, 45, 51, 52 and 63-70 under 35 U.S.C. § 102(a) or § 102(e) should be withdrawn.

The Examiner makes a number of points in rebuttal of Applicants' arguments on this issue presented in their previous paper. Applicants take the opportunity to address the Examiner's arguments here.

"Producer cells" v. "helper cells"

The Examiner criticizes the term "helper cell" and rebuts Applicants' arguments about this term by insisting that the portion of the specification relied upon by Applicants describes a "producer cell" transformed with the vector molecule and a helper RNA so as to produce recombinant alphavirus particles. Applicants submit that it is well-settled that the specification need not use the exact terms recited in the claims. Rather, the written description is sufficient if it provides enough disclosure to show one of ordinary skill in the art the inventor has invented what is claimed. *Union Oil of California v. Atlantic Richfield Co.*, 54 USPQ2d 1227 (Fed. Cir. 2000). Applicants further note that the Examiner clearly understood that the "producer cell" is one in which functions absent from the vector molecule are complemented by the "helper RNA" to produce recombinant alphavirus particles. Such a complementation is what is understood by the skilled artisan as a "helper cell" and thus Applicants submit that the Examiner in effect admits that the specification supports this term.

Should the Examiner wish to assert that the skilled artisan takes a "helper cell" to be permanently transformed with the DNA providing the complementing nucleic acid, Applicants point out page 10, lines 29-33, which describes various RNA molecules used in the invention as originating from, inter alia, *in vivo*

transcripts of a cDNA clone comprising "an inserted exogenous DNA fragment encoding a desired trait."

#### Plurality of helper cells

As to use of a plurality of helper cells, the Examiner asserts that the specification repeatedly uses the term "the helper RNA molecule" or "the helper vector" (emphasis is the Examiner's). Applicants address this issue in the Declaration of Dr. Liljeström and submit that, as a person of ordinary skill in the art at the time the invention was made, Dr. Liljeström's testimony establishes by the preponderance of the evidence that the scope of the disclosure of the specification encompasses a plurality of helper vectors and helper cells.

#### Characteristics of the helper nucleic acids

The Examiner further asserts that the specification fails to adequately describe the recitation in claim 45 that there is "at least one mutation in E1, E2 or E3". The Examiner argues that the scope of this phrase is broad and encompasses any type of mutation, such as insertions, substitutions, deletions, etc, and that the mutation can fall into the non-coding or coding region of the genes, etc.

Support for mutation in E1, E2 or E3 is provided by the specification at, e.g. page 10, lines 17-20. Here the

specification describes introducing a conditionally lethal mutation into the "structural" part of the viral genome, i.e. the capsid or one of the spike (E1, E2 or E3) proteins. Furthermore, beginning at page 34, Example 5 (illustrated in Figure 10) describes a conditionally lethal mutation in the p62 protein that is the precursor of the E2 and E3 spike proteins. P62 is normally cleaved by a protease *in vivo* to generate the E2 and E3 proteins (see, e.g. Fig. 1). In Example 5, the E3 part of the protein is changed by introducing a point substitution. Thus, there is specific description of a substitution mutation in the E3 protein. Still further, beginning at page 33, Example 4 of the specification describes insertion of a short oligonucleotide into the coding portion of the E2 protein. Thus, there is specific description of an insertion mutation into the E2 or E3 protein.

Applicants submit that the above description provides both generic and specific description of "mutation" of the E1, E2 or E3 protein.

As to claim 65, the Examiner mischaracterizes this claim. Claim 65 recites that one of the helper vectors encodes E1 and E2, not E1 and E3. Applicants thus again reiterate their position that the description of Figure 4, showing E1 and E2 transcripts as adjacent, supports their inclusion together in a helper vector or in a helper cell.

Applicants submit that the above explanation shows that the present specification indeed adequately describes the "subject matter of claims 43, 45, 51, 52 and 63-71 regarding helper cells, the limitations of more than one helper RNAs and the characteristics of the helper RNAs." Thus, the instant claims should be accorded at least the effective filing date of the present application of December 12, 1991 and the standing rejection of these claims over the Johnston reference should be withdrawn.

Applicants submit that the present application well describes and claims patentable subject matter. The favorable action of withdrawal of the standing rejections and allowance of the application is respectfully requested.

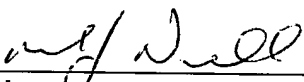
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a five (5) month extension of time for filing a response in connection with the present application. The required fee of \$2,160.00 is being filed concurrently with the Request for Continued Examination.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachement: Declaration under 37 C.F.R. 1.132